



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0335]

Advisory Committee; Obstetrics, Reproductive and Urologic Drugs Advisory Committee;
Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Obstetrics, Reproductive and Urologic Drugs Advisory Committee (formerly known as the Bone, Reproductive and Urologic Drugs Advisory Committee) by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Obstetrics, Reproductive and Urologic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the March 23, 2024, expiration date.

DATES: Authority for the Obstetrics, Reproductive and Urologic Drugs Advisory Committee (formerly known as the Bone, Reproductive and Urologic Drugs Advisory Committee) will expire on March 23, 2024, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Joyce Frimpong, Division of Advisory Committee and Consultant Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, email: ORUDAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services, FDA is announcing the renewal of the Obstetrics, Reproductive and Urologic Drugs Advisory Committee (the Committee). The Committee is a

discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug products for use in the practice of obstetrics, gynecology, urology and related specialties, and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of 11 voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of obstetrics, gynecology, urology, pediatrics, epidemiology, or statistics and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees, representatives or Ex-Officio members. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/human-drug-advisory-committees/obstetrics-reproductive-and-urologic-drugs-advisory-committee> or by contacting the Designated Federal Officer (see FOR FURTHER INFORMATION CONTACT). Due to a change in the Committee name and description of duties, a final rule will be published in the *Federal Register* amending 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. App.). For general information related to FDA advisory committees, please visit us at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: March 16, 2022.

Andi Lipstein Fristedt,

Deputy Commissioner for Policy, Legislation, and International Affairs.

U.S. Food and Drug Administration

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